



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/693,572

10/24/2003

Christopher T. Boyle

6006-108

2163

29335 7590 05/15/2012
ROSENBAUM & SILVERT, P.C.
1480 TECHNY ROAD
NORTHBROOK, IL 60062

EXAMINER

TON, MARTIN TRUYEN

ART UNIT

PAPER NUMBER

4126

NOTIFICATION DATE

DELIVERY MODE

05/15/2012

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

scotugno@rosenbaumsilvert.com

Office Action Summary	Application No.	Applicant(s)	
	10/693,572	BOYLE ET AL.	
	Examiner	Art Unit	
	MARTIN TON	4126	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/16/2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-7, 13, 15 and 26-28 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-7, 13, 15, and 26-28 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 10/24/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/16/2010 has been entered.

Claim Objections

1. Claim 1 is objected to because of the following informalities: Claim 1 is not dependent on a preceding claim; details on said issue can be found in MPEP 608.01(n). Appropriate correction is required.

Claim Rejections - 35 USC § 101

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 4126

3. Claims 1-7, 13, 15, and 26-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6733513 to Boyle et al. in view of Euteneuer (US 5207700).

- Regarding claims 1 and 27, US 6733513 describes a balloon catheter wherein the balloon consists essentially of at least one metal (claim 1), and a process for making said balloon through the use of vacuum depositing a metal onto a cylindrical mandrel (claim 5). Because the method of making the balloon catheter specifies that the balloon is made from a vacuum deposited metal, the balloon must inherently substantially comprise at least one vacuum deposited metal. Additionally, Figures 1 and 2A of the Euteneuer prior art reference shows a balloon catheter wherein the inflatable balloon is coaxially disposed about a catheter member such that a lumen is defined intermediate the catheter member and the inflatable balloon, which is considered to be an inflation lumen, with the balloon having an inner surface, and outer surface, and a wall thickness. The specific elements are shown in the figure below.

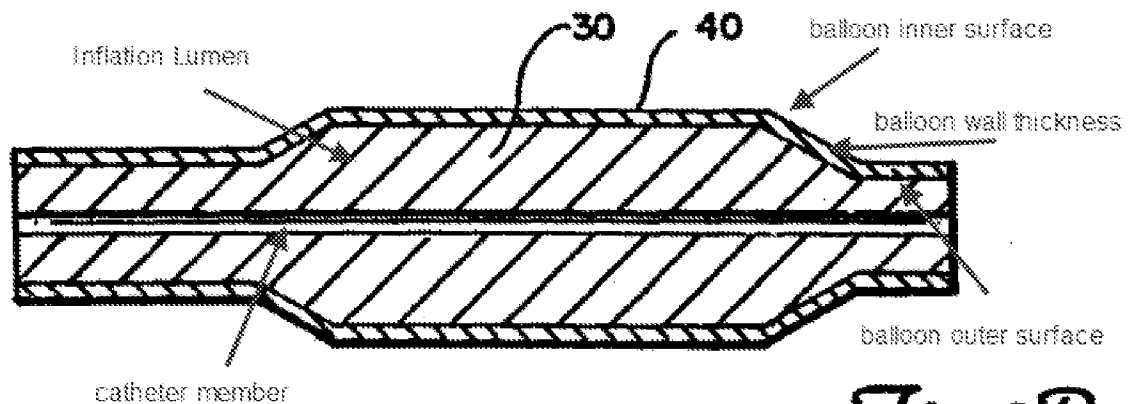


Fig. 2B

Art Unit: 4126

In view of the discussed elements, it would have been obvious to a person having ordinary skill in the art to make the balloon of the balloon catheter described in the Euteneuer prior art using the vacuum deposition method described in claim 5 of US 6733513 to add the conductive properties for transmitting energy delivered from an external force or radiopacity to the balloon, rendering claims 1 and 27 unpatentable due to double patenting.

- Regarding claim 2 of the present application, claim 2 of US 6733513 lists a group of metals that includes metals listed in the group described in claim 2 of the present application, rendering claim 2 unpatentable due to double patenting.
- Regarding claim 3, the Euteneuer prior art reference describes a wall thickness of about 0.0003 inches (Column 2, Line 58-66), or 7.62 μm , which falls within the range of 0.1 μm and 25 μm , rendering claim 3 unpatentable due to double patenting.
- Regarding claim 4 of the present application, claim 4 of US 6733513 describes that the balloon deflates under the influence of at least one of a shape memory, superelastic, or elastic property, rendering claim 4 unpatentable due to double patenting.
- Regarding claim 5, the Euteneuer prior art reference states that the catheter member, otherwise known as a catheter shaft, is preferably made of a metal or a polymer (Column 2, Line 51-57), rendering claim 5 unpatentable due to double patenting.

Art Unit: 4126

- Regarding claim 6 of the present application, claim 5 of US 6733513 describes the method of making a balloon catheter wherein a metal is vacuum deposited onto a generally cylindrical mandrel having a geometry desired for the inflatable balloon to form the inflatable balloon and removing the mandrel from the inflatable balloon, rendering claim 6 unpatentable due to double patenting.
- Regarding claim 7 of the present application, claim 1 of US 6733513 describes an inflation lumen of the catheter body in addition to a lumen intermediate the balloon and a central catheter member, which is considered to be an inflation lumen in itself, with the inflation lumen of the catheter body being in fluid communication with the second inflation lumen of the balloon. Furthermore, it is well known in the art that communication between these lumens must be accomplished by at least one port to allow for fluid to travel from one lumen to another, rendering claim 7 unpatentable due to double patenting.
- Regarding claim 13, claim 2 of US 6733513 recites a group of metals which includes radiopaque metals, such as gold, rendering claim 13 unpatentable due to double patenting.
- Regarding claim 15, claim 1 of US 6733513 states that the balloon is made of at least one metal. All metals inherently have conductive properties capable of transmitting energy from any source, rendering claim 15 unpatentable due to double patenting.
- Regarding claim 26, claim 5 of US 6733513 describes a method of making a balloon wherein a vacuum deposited metal is used to make a film of metal,

Art Unit: 4126

therein creating a single layer from a single vacuum deposited metal, rendering claim 26 unpatentable due to double patenting.

- Regarding claim 28, claim 4 of US 6733513 states that the balloon may deflate under the influence of at least one shape memory material, which implies that the balloon itself must substantially consist of a shape memory material, rendering claim 28 unpatentable due to double patenting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 7, 13, 15, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Abele (US 5860974).

The invention disclosed in the Abele prior art reference includes all of the elements of the listed claims. As seen in Figure 1 of the reference, the invention is a heart ablation catheter which comprises a catheter body and an inflatable balloon. The inflatable balloon (16) is coaxially disposed about a catheter member (10) such that a lumen is defined intermediate the catheter member and the balloon (Figure 5). This lumen is considered to be an inflation lumen. The balloon inherently has an inner surface, an outer surface, and a wall thickness. It also includes a conductive coating of vacuum deposited gold, a metal that has

Art Unit: 4126

both conductive and radiopaque properties, on the exterior of the balloon (Column 1, Lines 44-52), adding to the overall thickness of the balloon, and, depending on the thickness of the coating, would have the thickness substantially comprise a vacuum deposited metal, anticipating claims 1, 2, 13, 15, 26, and 27. Figure 1 also shows the catheter member including an inflation lumen in addition to the first inflation lumen intermediate the catheter member and balloon (18), and the inner lumen within the catheter must inherently have at least one port to allow for the fluid to flow from the first lumen into the second lumen, anticipating claim 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele (US 5860974) as applied to claims 1, 2, 7, 13, 15, 26 and 27 above, and further in view of Euteneuer (US 5207700).

The Abele prior art reference describes the invention as claimed in claim 1 and 27, but does not disclose a balloon wall thickness between about 0.1 μm and 25 μm or the catheter body being fabricated from a polymer or metal material. However, the Euteneuer reference describes a balloon catheter that includes a

Art Unit: 4126

balloon with a wall thickness of 0.0003 inches (Column 2, Line 58-66), or 7.62 μm , which falls within the range of about 0.1 μm and 25 μm , and also a catheter shaft, or body, made of metal or polymer material (Column 2, Line 51-57). Therefore, it would have been obvious to a person having ordinary skill in the art to make the balloon described in the Abele reference with a wall thickness of 0.0003 inches to help reduce the overall profile of the balloon catheter to enhance its deployment into a patient's vasculature, and to make the catheter body described in the Abele reference of a metal or polymer, because these are the most obtainable, economic, and commonly used materials used in medical devices, rendering claims 3 and 5 unpatentable due to obviousness.

6. Claims 4 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abele (US 5860974) as applied to claims 1, 2, 7, 13, 15, 26 and 27 above, and further in view of Wang et al. (US 5490839).

The Abele prior art reference describes the invention as claimed in claim 1 and 27; a heart ablation catheter which comprises a catheter body and an inflatable balloon, the inflatable balloon (16) coaxially disposed about a catheter member (10) such that a lumen is defined intermediate the catheter member and the balloon (Figure 5), wherein the lumen is considered to be an inflation lumen, and wherein the balloon inherently has an inner surface, an outer surface, and a wall thickness, but does not disclose a balloon wall thickness substantially comprising a least one shape memory material. However, the Wang et al. reference teaches a catheter balloon with a retraction coating made of a shape memory polymer

Art Unit: 4126

which deflates the balloon under the influence of the coating's shape memory properties (Column 3, Line 61 – Column 4, 21). Therefore, it would have been obvious to a person having ordinary skill in the art to utilize shape memory properties of a material as described in the Wang et al. reference to deflate the balloon of the Abele reference by using a shape memory metal to allow for consistency, resiliency, and heat initiated expansion and deflation of the balloon while continuing to maintain the balloon's conductive properties by using a shape memory metal material as opposed to a shape memory polymer material, rendering claims 4 and 28 unpatentable due to obviousness.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARTIN TON whose telephone number is (571) 270-5122. The examiner can normally be reached on Monday - Friday; EST 8:30 PM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lorraine Spector can be reached on (571) 272-0893. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

Application/Control Number: 10/693,572

Page 11

Art Unit: 4126

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. T./

Martin Ton

Examiner, Art Unit 4126

5/7/2012

/Lorraine Spector/

Primary Examiner, Art Unit 4126